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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,918

12/13/2005

John E. Hansen

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10/06/2006

EXAMINER

HAND, MELANIE JO

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WASHINGTON, DC 20006-1109

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/538,918	HANSEN ET AL.	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 84-110 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 84-110 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 84-110 are rejected under 35 U.S.C. 102(e) as being anticipated by Blakesley et al (U.S. Patent Application Publication No. 2002/0012982).

With respect to **Claims 1,84**: Blakesley teaches a swab 2 comprising gelatine particles and a support 1 fixed to said swab.

With respect to **Claim 85**: The swab 2 is a gelatine-based sponge.

With respect to **Claims 86,87,107**: Swab 2 comprises synthetic gelatine particles.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blakesley et al ('982).

With respect to **Claims 108,109**: Blakesely does not teach a mammalian or specifically a marine mammalian gelatine source, however the swab taught by Blakesley with a gelatine sponge from a marine mammalian gelatine source would be a swab which is substantially identical to the agarose gel swab taught by Blakesley, therefore it would be obvious to one of ordinary skill in the art to substitute a marine mammalian gel sponge for the agarose sponge taught by Blakesley with a reasonable expectation of success. Rejection under 35 U.S.C. 103 is indicated where prior art discloses product that appears to be either identical with or only slightly different from product claimed in product-by-process claim. See *In re Fitzgerald, Sanders, & Bagheri*, 205 USPQ 594 (CCPA 1980).

Claims 88 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blakesley et al ('982) in view of Ashton et al (U.S. Patent No. 5,387,208).

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With respect to **Claim 88**: Blakesley does not teach an absorption capacity for the gelatine material. Ashton teaches a gel material for absorbing water having an absorption capacity of at least about 20 g/g, which satisfies the limitation of claim 88. Ashton teaches that an absorbent article that includes the gelling absorbent material has improved dry and wet integrity, therefore it would be obvious to one of ordinary skill in the art to use the gelling material taught by Ashton having such absorption capacity for the gelling material of the swab taught by Blakesley.

With respect to **Claim 89**: Blakesley teaches an average pore size for the gelatine sponge of 0.1-10,000 microns, or 100 nm – 2 mm.

With respect to **Claim 90**: Ashton teaches a gelatine particle size of 50 microns -1 mm.

With respect to **Claim 91**: Blakesley teaches a kit comprising swab 2 and a cell-lysing agent, which constitutes an anti-microbial agent.

With respect to **Claim 92**: Blakesley teaches inorganic and organic buffers as neutral diluents.

With respect to **Claims 93,94**: Blakesley teaches making contact between swab 2 and a target.

With respect to **Claim 95**: Blakesley teaches the steps of wet sampling the target area with swab 2 comprised of a gelatine-based sponge and a support affixed thereto and dry-sampling the target area with swab 2.

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With respect to **Claims 96-98,102**: Blakesley teaches elution of target molecules while attached to the swab (i.e. transfer) by an aqueous buffer solution (first transfer medium).

With respect to **Claims 99,100**: The target molecules are peptides or proteins, i.e. organic molecules.

With respect to **Claim 101**: The transfer to the first medium, the buffer solution, is followed subsequently by addition of the lysing agent, which accomplishes digestion of the gelatine particles.

With respect to **Claim 103**: The cell lysing agents comprise chromatographic resins having enzymes bonded thereto.

With respect to **Claim 104**: The cell lysing process accomplishes digestion of the target cells by being filtered through a cell membrane.

With respect to **Claim 105**: The buffer solution acting as the first transfer medium is a neutral diluent.

With respect to **Claim 106**: Blakesley teaches culturing the cells collected on swab 2 in a growth medium.

With respect to **Claim 110**: Blakesley teaches agarose gelatine which is found in seaweed which is a vegetable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

MJH
September 30, 2006

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

